DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

AUG 28 2000

Robert A. Dormer, Esquire
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Re. Docket No. 98N-0337
Application for Exemption

Dear Mr. Dormer:

This letter is in response to your Application for Exemption dated January 28, 2000, and amended on August 22, 2000, on behalf of Block Drug Company (Block), Inc. You requested an exemption from certain of the over-the-counter (OTC) drug product labeling requirements in 21 CFR 201.66 for Block's BC analgesic powder containing two doses packaged inside an outer envelope approximately 3 5/8 inches by 2 3/8 inches in size.

Block raised several general issues that we would like to address. First, Block noted that the front of the package is the principal display panel (PDP) and the back side of the envelope is the only space available for the required labeling, but not all of the back side is available because the flaps that allow the envelope to close must contain the UPC symbol and the tamper-evident statement.

We disagree with Block's position that the back side of the envelope is the only space available for the required labeling or that the flaps must contain the UPC symbol. The agency addressed this very point in § 201.66(b)(12) of the final rule, which provides that the total surface area available to bear labeling means all surfaces of the outside container of the retail package or, if there is no such outside container, all surfaces of the immediate container or container wrapper except for the flanges at the tops and bottoms of cans and the shoulders and necks of bottles and jars. The formula in § 201.66(d)(10) for using the modified labeling format (i.e., determining whether more than 60% of the total surface area available to bear labeling is required) is consistent with the idea that 40% of available labeling space is generally reserved for the UPC symbol and PDP (64 FR 13254 at 13267).

When labeling the envelope of this specific product, the space available for the required labeling is <u>not</u> limited to a portion of the back of the envelope package. We wish to point out that the current labeling for this product uses about ¾ of an inch (approximately 30%) of the width of the PDP for the product's uses or indications information. There is no uses or indications section on the back side of the envelope. This is required labeling information, and the company has already included it on the PDP. We do not consider it appropriate to expect the required Drug Facts labeling to be included only on a portion of the back panel when the currently marketed product utilizes the PDP for a portion of the required labeling. Further, the flaps on the back of the package currently bear labeling information, and the area available to bear the Drug Facts labeling would include these flaps. The UPC symbol, which currently appears on one of the flaps, is not part of the

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FDA required information for OTC drug products. As noted above, 40% of the available labeling space is generally reserved for the UPC symbol and PDP. Therefore, either the UPC symbol should be moved to the PDP or if other required labeling appears on a portion of the PDP, the UPC symbol may remain on one of the flaps. In either case, the flaps should be considered as available space to bear some of the required Drug Facts labeling when doing the 60%/40% space allocation.

Block stated that its analgesic powders have a long history of safe and effective use; the typical consumer of these products has been using them for many years; it is unaware of any consumer injury or complaints due to inability to read the label; and it is unaware of any other evidence that these products present a risk to public health or safety. Block appears to be using these statements to infer that this product may not need to meet some or all of the Drug Facts labeling requirements. Block also infers that if the agency denies Block's exemption requests, there is a potential that this product will no longer be able to be marketed.

The new Drug Facts labeling is intended to provide continued safe and effective use of these OTC drug products. The Drug Facts labeling will provide a uniform presentation of information for both old and new users of these products, including the new information that has been added to product labeling in recent years (e.g., alcohol warning and allergy alert). These powder products contain aspirin (and some also contain acetaminophen), ingredients that have been associated with many adverse events. While these products are available OTC, their labeling should not in any way minimize the adverse events that can occur. Continued availability of these products should involve both old and new users being readily able to read the product's labeling information to promote safe and effective use of the product.

In the Application for Exemption, Block indicated that it is unable to fit all of the required labeling on this outer envelope using either the standardized or the modified labeling format in 21 CFR 201.66. Block discussed other methods of modifying the packaging (tear pad, outsert label, folded card, skin pack, and riser card) and the reasons why these methods were rejected. Block presented two alternative labeling/packaging options for consideration.

Exemption Option 1

Block's first labeling alternative included a proposed exemption from the following formatting requirements: (1) Left justification for all subheadings (§ 201.66(d)(1)), (2) type size requirements (§ 201.66(d)(2) and (d)(10)(ii)), (3) information described in § 201.66(c)(5) not appear on the same line as the Warning(s) heading (§ 201.66(d)(6)), and (4) hairlines that are to precede each of the subheadings in § 201.66(c)(5) (§ 201.66(d)(8)).

Exemption Option 2

The second labeling alternative included a proposed exemption from printing all of the required information on the outside container or wrapper of the package. Under this option, Block proposes to modify the current package to add a flap or a fifth panel that

would fold out to display the information that cannot fit on the back of the current package. Using this approach, the labeling would conform with all the other content and format requirements of § 201.66. Because the entire package is shrink-wrapped to make the product tamper-evident, as well as to improve stability, Block points out that the continuation of the Drug Facts information on the inside of the flap or folded fifth panel would not be visible until the shrink-wrap is removed and the flap or panel is unfolded. However, Block maintains that the entire Drug Facts information would appear at the point of purchase in the standard labeling format on the tray located on the store shelves displaying the product.

Division's Response to Option 1

We note the labeling examples where Block increased the envelope size to accommodate all the required labeling (both standard format and modified format). We concur with your statement that this approach produces an undesirable result. However, we disagree that the package size would need to more than double to accommodate the required labeling.

In response to industry submissions of products that reportedly would not fit the new labeling format, the agency prepared a mock-up of the individual envelope for Goody Headache Powder using the § 201.66(d)(10) modified format. These mock-ups were placed in the docket for the final rule and a copy of the Goody Headache Powder envelope mock-up is enclosed. As you can see, there is no need to double the package size because the agency has already determined that the modified labeling format can be used for this product. Further, as you will note from the mock-up, although we were not able to get all the required information within the package space, we did not need much additional space. However, the space that we used was approximately 2 7/8 inches by 2 5/16 inches, which is less than the total 3 5/8 inches by 2 3/8 inches size of the envelope of the BC powder product. We have some further suggestions on this subject later in this letter.

As discussed in the OTC labeling final rule (64 FR 13254 at 13268), products that are unable to meet the labeling format described in 21 CFR 201.66(d)(1) through (d)(9), or the modified format authorized under 21 CFR 201.66(d)(10), will be expected to be reconfigured to meet the format requirements of the OTC labeling regulations. The analysis of impacts discussion in the final rule contemplated the cost of redesigning a product label if necessary. The agency stated that it will not routinely grant exemptions or deferrals, particularly for print size, under 21 CFR 201.66(e) for products that claim to be too small to meet the requirements of the labeling final rule.

The agency reiterated its position in a February 4, 2000 response to a citizen petition submitted on behalf of the Consumer Healthcare Products Association (CHPA). In that letter (copy of pertinent part enclosed), the agency discussed in detail why type size smaller than 6 point will not be allowed for products using the modified labeling format. Accordingly, we are not providing an exemption for type size smaller than 6-point.

At this time, we ask that Block redraft its proposed labeling for this product using more of the total surface area available to bear labeling. By beginning the Drug Facts

information on the PDP, it may be possible to fit the "Drug Facts" heading and the active ingredients, purpose, and uses information on the front of the envelope. As noted above, the agency was able to fit most of the information for a package of Goody Headache Powder into a 2 7/8 inches by 2 5/16 inches space using 6 point Helvetica narrow text. However, the agency did its mock-up with the package in a different layout than Block uses. In addition, the agency did its mock-up without considering the use of columns on the back panel. Likewise, Block did not use a column format in any of the examples it provided. Block should determine if the column format using the existing product configuration and the flap space would result in a better fit of the remaining labeling information on the back of the envelope. In addition, Block should evaluate whether it could expand the left and right margins of the columns that appear on the back of the currently marketed product to be closer to the flaps to gain additional labeling space. Finally, if the last portion of the required Drug Facts labeling would fit on one of the flaps, Block should consider using that space for the information.

Depending on how some of the Drug Facts information fits on the PDP, Block may want to move the net content statement to the current area of the "red" stripe if that appears immediately above where the "Drug Facts" information might begin. The division would be willing to consider an exemption to the requirement that the net quantity of contents appear within the bottom 30% of the PDP if that is necessary to accommodate the required "Drug Facts" labeling. We would see no problem with that information appearing in the bottom 40% to 45% of the PDP.

The division notes that the current color of the labeling at the bottom of the PDP is white print on a blue background. The back of the envelope has blue print on a white background. Section 201.66(d)(3) requires that the type for the "Drug Facts" information shall be all black or one color on a white or other contrasting background. The division acknowledges that Block may consider the color of the PDP to be trade dress for this product. Accordingly, the agency would consider an exemption request from the one color requirement of § 201.66(d)(3) if Block included "Drug Facts" labeling on the PDP but wished to retain the product's existing trade dress.

Division Response to Option 2

We note Block's statement concerning its second option that consumers will still be able to view all of the labeling information in the required format on the tray that is placed on the store shelves to display the product. We have a number of concerns about this option.

First, section 201(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(k)) defines the term "label" as a display of written, printed, or graphic matter upon the immediate container of any article. This section of the Act further states that "a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the **retail package** [emphasis added] of such article, ..." Section 502(c) of the Act (21 U.S.C. 352(c)) states that a drug or device shall be deemed misbranded "If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon ... and in such terms as

to render it likely to be read and understood by the ordinary individual under customary conditions of **purchase** [emphasis added] and use." The requirements of section 502(c) of the Act are addressed in 21 CFR 201.15 entitled "Drugs; prominence of required label statements."

We are concerned that including labeling information on a product tray does not meet the requirements of sections 201(k) and 502(c) of the Act for several reasons. First, the tray is not the "retail package" of the article being sold. Second, there is no assurance that retailers will retain the tray, especially when only a few packages remain in it for sale. In addition, there is no legal requirements for retailers to retain this tray or even place it in a location where it will be visible or accessible to consumers who wish to purchase the product initially present in it. Third, as noted in the exemption request, these powders and especially the two dose package at issue here are typically sold in convenience stores and gasmarts. Many transactions at gasmarts, particularly in the evening and at night, are via a window at the gasmart where the consumer would not have access to even see the tray. Fourth, there is some concern whether the type sizes for the Drug Facts labeling will be sufficient for consumers to read the labeling information printed on a product tray. It is assumed that consumers hold a product in their hand a short distance from their eyes to read the product labeling. If consumers cannot pick up a tray or are unable to get close enough to where the tray is displayed in a store to read the labeling, the type sizes required in § 201.66(d)(2) and (d)(3) may not be sufficient for a product tray. Finally, this option does not allow the consumer to see all of the labeling information at the time of purchase because, when the tray is not available, the fifth panel contains information that is not visible. Thus, we have concerns whether a display tray bearing all of the required labeling information (when the immediate container of the retail package included in that display tray does not bear the information in a manner that is visible and readable at the point of purchase) complies with the requirements of the Act. However, we are willing to consider any further information you may be able to provide, regarding how an approach of this type could meet the requirements of the law and applicable regulations.

In conclusion, the labeling requirements in 21 CFR 201.66(c) state that the outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper, shall contain the title, headings, subheadings, and information set forth in 21 CFR 201.66(c)(1) through (c)(8) (and (c)(9) (if included). Block's proposed modification of the envelope package to include the Drug Facts information on the inside of a flap or folded fifth panel, which would not be visible until the shrink-wrap is removed and the flap or panel is unfolded, would not be in compliance with the labeling requirements. However, if Block can design labeling using a fifth panel where the Drug Facts information is visible at the point of purchase, such a design would be acceptable.

Observations and Conclusions

We have reached our decision without the need to consider the cost information that Block considers confidential. We do not believe that it is necessary for Block to include cost information should it supplement this Application for Exemption.

There currently is no final monograph for OTC internal analgesic drug products, and Block is not required to convert the labeling of this product to the new format at this time. Until a final monograph is published, Block does not need to implement the new labeling requirements until the first major labeling revision after May 16, 2002 [see the FEDERAL REGISTER of June 20, 2000 (65 FR 38191) where the compliance date for implementing the new labeling format was extended from May 16, 2001 to May 16, 2002] or by May 16, 2005, whichever occurs first. Nonetheless, the agency encourages early implementation of the new Drug Facts labeling, and the division would be willing to work with Block to develop mutually acceptable labeling for this product in the interim time before implementation will be required. If you are unable to resolve this matter satisfactorily at the division level, you should follow the procedures in the agency guidance entitled "Guidance for Industry Formal Dispute Resolution: Appeals Above the Division Level (February 2000)."

Block may wish to consider our suggestions provided earlier in this letter and resubmit draft labeling for our consideration. Block may also determine that there are other graphical or packaging techniques that would accommodate the required labeling information. However, if Block's efforts to better utilize the available labeling space are unsuccessful, we anticipate that only a very small increase in package size may be necessary, based on the labeling mock-up the agency is enclosing for another one of these powder products.

We hope our comments will help Block to prepare its new labeling for small packages of its analgesic powder products.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosures

Goody Headache Powder

Combination Product Using Section 201.66(d)(10) Modified Format*
[Individual Envelope]

Front

2 3/8 inches

PDP Space

Drug Facts

Active ingredients (in each powder)	Purpose
Aspirin 500mg	Pain reliever
Acetaminophen 260mg	Pain reliever
Caffeine 32.5mg	Pain reliever aid

Use temporarily relieves minor aches and pains due to:
■ colds ■ headache ■ minor arthritis pain

Supposed to be 3 5/8 inches

Back

Drug Facts (continued)

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported with aspirin.

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen, aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.

Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have ■ asthma ■ ulcers ■ bleeding problems ■ stomach problems that last or come back, such as heartburn, upset stomach, or pain

Ask a doctor or pharmacist before use if you are taking a prescription drug for: ■ diabetes ■ gout ■ arthritis ■ anticoagulation (blood thinning)

Stop use and ask a doctor if ■ allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts for more than 10 days ■ redness or swelling is present ■ new symptoms occur ■ ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

grey line is actual size of product

Directions ■ do not take more than directed
■ adults and children 12 years and over: place 1 powder on tongue every 4 to 6 hours. Follow with liquid. May stir powder into glass of water or other liquid and drink; not more than 4 powders in 24 hours.
■ children under 12 years: ask a doctor

Inactive ingredients: lactose, potassium chloride

* Note: 9 point Helvetica Narrow Bold Italic Title
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6 point Leading

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 4, 2000

Bruce N. Kuhlik
Michael S. Labson
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20044-7566

Re: Over-the-Counter Drug Labeling (Docket No. 98N-0337/CP2)

Dear Messrs. Kuhlik and Labson:

This letter is in response to the petition submitted on October 1, 1999, on behalf of the Consumer Healthcare Products Association (CHPA). The petition, submitted under 21 CFR 10.30, requests a two-year extension of time for compliance with the agency's final rule on the labeling of over-the-counter (OTC) drug products, 21 CFR 201.66. *See* 64 FR 13254 (Mar. 17, 1999). The rule established a standardized format for presenting required OTC drug labeling information. It is intended to assist consumers in reading and understanding OTC drug labeling, in selecting among various products, and in using these products safely and effectively.

The rule went into effect on May 16, 1999.[1] However, for the large majority of products, compliance with the rule is not required until, at the earliest, May 16, 2001 (the "primary implementation date"). *See* 64 FR at 13274.

CHPA requests a two-year extension of the primary implementation date to May 16, 2003. Also, for those products that must immediately begin to comply with the rule (namely, OTC drug products approved after May 16, 1999, under new drug or abbreviated new drug applications), CHPA requests a stay of the rule "until FDA resolves currently open implementation issues and companies are given sufficient time to incorporate FDA's clarification into the label . . . ." CHPA Petition ("Pet.") at 3.

The primary basis for the petition is the claim that "[c]ritical issues concerning the label formatting under the new rule are unresolved," and that companies cannot begin converting to the new format until these issues are resolved. Pet. at 7. As noted in the petition, the agency's economic impact analysis in support of the final rule generally assumes a 2-year implementation

[1]On April 15, 1999, the agency published a correction to the effective date of the rule (64 FR 18571).

amended to allow more ways to use columns, would be to file a petition under 21 CFR 10.25(a).

B. Trade Dress

The agency believes the technical amendment document, published on January 3, 2000 (65 FR 7), resolves the questions that CHPA and others raised, following publication of the final rule, about the use of certain light on dark combinations of print. Therefore, an extension of the primary implementation date is not needed to allow for further discussion of this issue.

C. Type Size

The final rule requires a minimum type size of 6 points when presenting information in the "Drug Facts" labeling. 21 CFR 201.66(d)(2); *see generally* 64 FR at 13264-65. Since publication of the rule, CHPA has made several presentations on the issue of type size. CHPA estimates that as many as 30 percent of OTC stock keeping units cannot comply with the rule, and that type size is the most significant factor in determining whether the new labeling will fit onto an existing package.

Accordingly, CHPA has asked the agency to delay implementation of the rule to consider the use of smaller type sizes, especially for small packages. CHPA has argued that data in the record support a minimum type size of 4.5 points. Also, CHPA insists the agency lacks an adequate basis to require a 6 point minimum. Finally, CHPA has continued to raise the need for "type size parity" across all FDA regulated products. *See, e.g.*, Ex. 1; Ex. 2 at 6, slide 12. For the reasons discussed below, the agency does not agree that additional time is needed to consider type size issues.

1. General Factors

FDA has been considering the issue of type size for OTC drug products since at least 1990, when the Pharmacists Planning Service (PPS) petitioned FDA to set minimum standards for OTC drug labeling. Among other things, the petition emphasized that significant numbers of older adults have been hospitalized due to adverse drug reactions involving OTC drugs, and that most people (especially the elderly) are unable to read the print on OTC drug labeling. 62 FR at

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comments to the proposed rule, columns were listed as one many factors that may affect readability. The agency, however, found no substantive discussion by CHPA of the use of columns or the idea of allowing information under certain headings to be divided into columns ("columns within columns"). None of the labels appended to CHPA's comments, in which CHPA suggested modifications to FDA's proposed format, shows the use of "columns within columns." *See* CHPA comments, App. E. The "Recommended Format" submitted by CHPA with its comments, App. F, does not show or suggest the use of columns.

9028.

The issue of assuring readability for elderly consumers has been a significant consideration throughout this process. Although the elderly comprise 12 to 17 percent of the population, they consume about 30-50 percent of all drug products. 62 FR 9024, 9027. As discussed in a 1994 study, a significant number of elderly consumers (60 yrs or older) could not adequately see the print on certain OTC product labels due in part to small type sizes and horizontal letter compression. *See* 62 FR at 9028 (*citing* Ex. 3); *see also* Sept. 29, 1995, Public Hearing on Over-the-Counter Drug Labeling Transcript at 31, FDA Docket No. 95N-0259 (hereafter Transcript) ("[T]he elderly are more likely to use over-the-counter medications, more likely to have a higher incidence of medical conditions that may be adversely affected by the inappropriate use of medications, and more likely to be taking other medications that may have adverse interactions with certain over-the-counter medications.").

Second, the goal of this proceeding has been to set standards for clear, consistent, easy-to-read drug labeling, and to minimize the "cognitive load" that drug labeling places on lay consumers. *See, e.g.*, 64 FR at 12355. Under section 502(c) of the Federal Food, Drug, and Cosmetic Act, drug labeling must be sufficiently prominent and conspicuous "as to render it *likely to be read and understood* by the ordinary individual . . ." 21 U.S.C. 352(c) (emphasis added); *see* 64 FR 9043. Marginal type sizes, or type sizes that are legible only at threshold levels, make it *less likely* that a consumer will begin to read the labeling, let alone read it thoroughly.

Third, as discussed below, the agency carefully considered industry practices in setting a minimum type size for OTC drug labeling, to help ensure the adoption of an attainable standard.

2. CHPA's Approach

CHPA's central study in support of the argument that 4.5 point type is an appropriate minimum standard for OTC drug labeling is Sidney Smith's 1979 article, "Letter Size and Legibility" (attached as Ex. 4).[4]

Smith studied "display legibility" using a variety of test materials, none of which appears to have included drug labeling. Ex. 4 at 665. Some of Smith's samples consisted only of a single word. *Id.* at 667. Moreover, the subjects in the study were asked only to identify the

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[4]CHPA referenced the Smith study in its comments to the proposed rule (*see* CHPA comments to proposed rule, App. H.) and in correspondence with the agency prior to the proposed rule. *See, e.g.*, Ex. 5. Although Smith and the other studies discussed in this section are already part of the record of this proceeding, the agency them as exhibits to this response, for the convenience of the reader.

absolute "legibility limit" for a given piece of display material. *Id.* at 666 ("The only measure taken was the legibility limit."). Viewers were not asked to specify a comfortable or preferred viewing distance, nor were they asked to identify the distance from which the material could be read with ease. Also, Smith did not record the age of his test subjects. There is even some suggestion that most may have been under 30 years of age. *Id.* at 668.

In contrast, the focus of this proceeding has been on labeling that consumers are *likely* to read and understand, from beginning to end, rather than on the threshold levels at which consumers can first begin to see printed material. *See* 21 U.S.C. 352(c). There is an important distinction between what a consumer is able to see, and what a consumer is likely to try to read – from beginning to end, with minimal error. As Smith cautioned:

> In practical display applications, however, it is not wise to design to the limits of visual acuity. An engineer will not design a bridge to meet minimum loads, but instead multiplies the strength of supporting trusses by some safety factor so that the bridge can be crossed with greater confidence. A display designer should also include some safety margin, specifying a letter size large enough to be read with confidence.

Ex. 4 at 662 (emphasis added).

Finally, following publication of the final rule, CHPA has continued to reference Smith for the idea that "98% of test subjects could read 4.5 point type at a distance of 13 inches." Ex. 6 at 7. In fact, Smith found that 98 percent of his test subjects could read copy that subtended a visual angle of 0.0046 radians.

According to CHPA, a visual angle of 0.0046 radians corresponds to a letter height of 0.06 inches at a viewing distance 13 inches,[5] and a letter height of 0.06 inches corresponds to a point size of 4.5. Ex. 5 at 2. However, a type size of about 6 to 8 points would be needed to present text that is generally 0.06 inches in height. This is because, as CHPA has stated, letters set in 4.5 point type are *not* 0.06 inches high.[6] *Id.* CHPA's submissions to the agency state that point size is a measure of the total height from the bottom of the lowest letter to the top of the highest letter, and that the upper case letters in 4.5 point type are usually only .042 inches or about 3 points. *Id.* Lower case letters in 4.5 point type would be even smaller – about half the

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[5]Although CHPA assumes a viewing distance of 13 inches, other materials cited by CHPA suggest 16 inches as the appropriate benchmark for "reading distance." Ex. 5 at 3 (citing Holt, G., *et al..*, "OTC Labels: Can Consumers Read and Understand Them?" 11 *American Pharmacy* 51 (Nov. 1990)). Using 16 inches, the letter height would be 0.0736 inches.

[6]Type sizes are designated in units called points. There are approximately 72 points to one inch. Each point measures 0.0138 of an inch.

point size or 0.03 inches. Therefore, to achieve the level of legibility that CHPA relies on from the Smith study, one would need to use text that is more than 6 points (assuming a viewing distance of 13 inches and the use of all upper case letters); or 8 points (assuming a viewing distance of 13 inches and the use of primarily lower case letters)[7]. Added to that, Smith found that letter sizes intended for close viewing, such as consumer labeling, may need to be larger in size than one would derive from a measure of the limits of visual acuity. *Id.* at 668.[8]

For these reasons, the agency disagrees with CHPA that the Smith study supports the use of 4.5 point type in OTC drug labeling. Indeed, Smith would support the use of a larger type size (6 point *or greater*) for consumer-directed drug labeling.

CHPA has also directed the agency to "the definition of visual acuity" to support the use of 4.5 point type in OTC drug labeling. *See, e.g.*, Ex. 5; Ex. 7. According to CHPA, a person with 20/20 vision can read text 0.019 inches high at a distance of 13 inches (equal to 1.7 point type), a person with 20/40 vision can read text 0.037 inches high (equal to 3.3 point type), and a person with 20/55 vision, according to CHPA, would be able to read 4.5 point type. *See* Ex. 5 at 3; *see also* Ex. 7 at 1.

For reference, the following sentences are set in 1.7, 3.3, and 4.5 point type:[9]

This sentence is in 4.5 point Times New Roman type

Each of these type sizes – if one accepts CHPA's assumptions – represents the threshold limit at which a person with a given visual acuity can begin to see text. They do not represent type sizes which can be read with ease. *See* Ex. 4 at 662 ("Design standards for visual displays generally

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[7]The OTC labeling rule requires primarily the use of *lower case* letters. *See* 21 CFR 201.66(d)(1).

[8]Smith also found that 100 percent of his subjects could read a letter size of 0.007 radians. *Id.* at 667. Using CHPA's method of converting this figure to a point size, Smith found that 100 percent of his test subjects were able to read 6.6 type at a distance of 13 inches. If one adjusts for the use primarily of lower case letters and a viewing distance of 16 inches, one would need to use a type size of more than 12 points to attain the level of legibility found by Smith.

[9]The following sentences are set in 6, 8, and 10 point type:

This sentence is in 6 point Times New Roman type.

This sentence is in 8 point Times New Roman type.

This sentence is in 10 point Times New Roman type.

recognize the need for a safety margin, and specify letter sizes larger than those at the limits of visual acuity."). Moreover, if one adjusts for a standard reading distance of 16 inches, and takes into account the use of primarily lower case text, each of these types sizes would have to be adjusted *upward*. The agency also notes that type size is only one factor that determines readability (*see* 62 FR at 9028), and that OTC labeling – which often consists of extensive and complex text – can be especially demanding for the reader.[10]

At best, CHPA's approach may help to establish a base from which to develop specific minimum type sizes for specific categories of products. As discussed below, the agency has allowed the use of the smallest readable type size in certain contexts (*see* section II.C.4, below). For OTC drug labeling, however, there is ample basis to require a larger size.

3. The Industry Standard

A key starting point for FDA in setting an appropriate minimum type size for OTC drug labeling was to consider current industry practice. At the agency's September 1995 public hearing, CHPA testified that most of the OTC drug industry had already adopted 6 points "*or better*" as the standard:

> We have done a label survey of our members looking at 2,000 labels and over 95 percent were at six point or better, and I think one of the practicalities is that there is a huge amount of information that is required on some of these labels. The particular diphenhydramine prototype that is in Appendix C [is] done at around six points, if you do that at seven points [it] will not fit the package. So, we recommend adopting the current industry practice."

Transcript at 108 (emphasis added).[11]

The agency, in turn, incorporated the industry standard into the OTC labeling rule after hearing additional testimony and after reviewing several studies confirming the readability of 6

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[10]In contrast, a study submitted by the American Pharmaceutical Association with a comment to the proposed rule evaluated the readability of 9 OTC drug labels with type sizes ranging from 4 to 11 points. Ex. 8. The study found that subjects needed at least 20/30 vision to read OTC drug labeling in 4 point type and 20/40 vision to read labeling in 6 point type. Only one of the labels (presumably, a label set in 11 point type) could be read accurately by those with a visual acuity of 20/50. Ex. 8 at 51.

[11]In its written submission to the public hearing, CHPA noted that "as an absolute minimum, 4.5 print type is reasonable for OTC labels, though not often used. Six point type is commonly used and preferred." Ex. 9 at 17.

point type for OTC drug products. For example, the National Consumers League (NCL) testified at the September 1995 hearing on an "investigative survey" of OTC drug labeling. In the study, 60 adults were asked to assess the readability of OTC products ranging in size from 4.0 to 6.5 point type. Ex. 10 at 3. As the agency noted in the rulemaking, NCL found that only 32 percent of the subjects age 51 and older were able to read OTC drug labeling set in 4.5 point type. 64 FR at 13265. Among the labels tested by NCL, the one set in 6.5 point type proved best, with 75 percent of the subjects age 51 and older, and 94 percent of the subjects under age 51, able to read it. On the other end of the spectrum, none of the subjects age 51 and older was able to read one of the labels set in 4 point type, and only 25 percent of the subjects under age 51 were able to read the label. Ex. 10 at 8. Thus, the NCL survey raises concerns about the readability of type sizes around a 4.5 point range and, at the same time, supports the use of type sizes in the 6.5 point range.[12]

The Watanabe study, cited by the agency in the rulemaking, also supports the use of a 6 point or better type size. Dr. Watanabe sampled 92 consumers, 60 years of age and older, using three labels – two set in 3.3 point type and one set on 6.7 point type. Ex. 3 at 33; *see also* 64 FR at 13265. In addition to showing that horizontal letter compression is a significant factor in determining readability, the Watanabe study concluded that a vertical type size of at least 6.7 points should be used in OTC drug labeling.[13]

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[12]At the November 23, 1999, feedback meeting, CHPA stated that the NCL study supported the use of less than 6 point type. Ex. 2 at 6, slide 11. The 5 point label tested in the NCL survey performed at the same level as one of the labels set in 6 point type. Forty-eight percent of the subjects age 51 and older either could not see the text on either label or found it too hard to read. Factors, such as color contrast, layout, or letter compression, may have accounted for these results. However, a second label tested by NCL, set in 6 point reverse type significantly outperformed the other labels. Sixty-eight percent of the older subjects and 91 percent of the younger subjects were able to read it. Ex. 10 at 9.

[13]At the November 23, 1999, feedback meeting, CHPA asserted that the Watanabe study "showed little difference in readability between 6.7 and 3.3 point type." Ex. 2 at 6, slide 11. We disagree. In a comparison of one of the 3.3 point labels to the 6.7 point label, Dr. Watanabe found that approximately 30 percent of the subjects were unable to either start *or finish* reading the 3.3 point label. Only 2 percent were unable to read the 6.7 point label. In a comparison of the other 3.3 point label with the 6.7 point label, Dr. Watanabe found only a small statistical difference in readability, concluding that the horizontal letter compression on the 3.3 point label compensated significantly for the smaller type size. However, Dr. Watanabe also concluded that "subjective observations by both subjects and researchers indicate that greater effort was expended in reading the smaller print [on this label]," and that "[t]his suggests that letter size approximating the [6.7 point type size] should be used." Ex. 3 at 35.

The agency also received numerous comments from consumers, consumer groups, and health professionals in favor of adopting 6 point or larger as the minimum standard. *See, e.g.*, FDA Docket No. 96N-0420, C103; C104; C467. Consumer preferences and comments are significant in this proceeding, given the statutory directive to develop labeling that consumers will be "*likely*" to read.

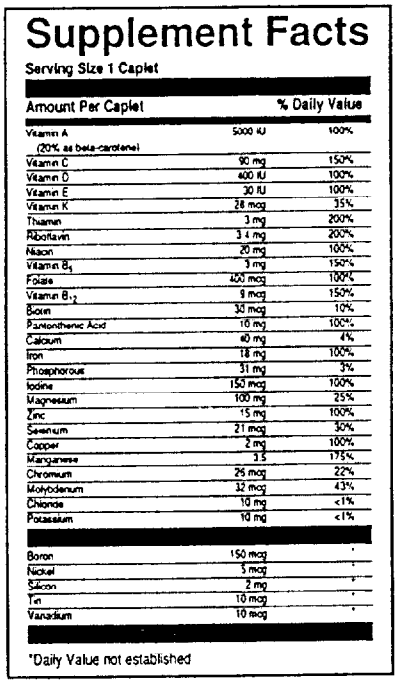
4. "Parity"

Finally, at the November 23, 1999, feedback meeting and at several other public meetings following the final rule, CHPA has emphasized the need for "consistency and fairness across FDA regulated consumer products." As noted in comments to the proposed rule, the agency allows certain dietary supplement products to use a minimum 4.5 point type. 21 CFR 101.36(i). The agency has also allowed letters no less than 1/16th of an inch for the listing of ingredients in cosmetic products, or 1/32 of an inch in limited circumstances. 21 CFR 701.3(b) and (p).

The agency carefully considered this issue in the final rule and did not find it to be decisive. 64 FR at 13265. As the agency outlined in the rule, factors such as the nature and quantity of the information required, and the manner in which the information is presented, may allow for the use of different labeling specifications. In some contexts, there is often little required information presented on the labeling (either a few words or a single sentence), and there is adequate white space to enhance readability, putting less of a demand on the user to read the information.

This point is illustrated below. Figure 1 shows a multi-ingredient dietary supplement product with the required text presented in 4.5 point type, compared with a multi-ingredient OTC drug product. The OTC drug product follows the modified format permitted under 21 CFR 201.66(d)(10), except that for purposes of illustration the drug product uses 4.5 point type to present the required text rather than the required 6 point minimum. Figure 2 compares the multi-ingredient OTC drug product in 4.5 point type versus 6 point type. Figure 2 illustrates the benefit of a larger type size in OTC drug labeling. Both figures use optimal color contrast (black text on a non-glossy white background).

Figure 1

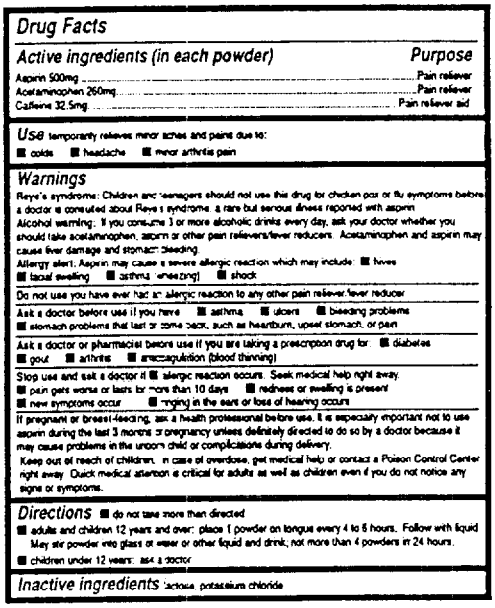


Supplement Facts

Serving Size 1 Caplet

Amount Per Caplet		% Daily Value
Vitamin A (20% as beta-carotene)	5000 IU	100%
Vitamin C	90 mg	150%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Vitamin K	28 mcg	35%
Thiamin	3 mg	200%
Riboflavin	3.4 mg	200%
Niacin	20 mg	100%
Vitamin B_6	3 mg	150%
Folate	400 mcg	100%
Vitamin B_{12}	9 mcg	150%
Biotin	30 mcg	10%
Pantothenic Acid	10 mg	100%
Calcium	40 mg	4%
Iron	18 mg	100%
Phosphorous	31 mg	3%
Iodine	150 mcg	100%
Magnesium	100 mg	25%
Zinc	15 mg	100%
Selenium	21 mcg	30%
Copper	2 mg	100%
Manganese	3.5	175%
Chromium	25 mcg	22%
Molybdenum	32 mcg	43%
Chloride	10 mg	<1%
Potassium	10 mg	<1%
Boron	150 mcg	*
Nickel	5 mcg	*
Silicon	2 mg	*
Tin	10 mcg	*
Vanadium	10 mcg	*

*Daily Value not established



Drug Facts

Active ingredients (in each powder) — *Purpose*

Aspirin 500mg ..... Pain reliever
Acetaminophen 260mg ..... Pain reliever
Caffeine 32.5mg ..... Pain reliever aid

Use temporarily relieves minor aches and pains due to:
■ colds ■ headache ■ minor arthritis pain

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported with aspirin

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen, aspirin or other pain relievers/fever reducers. Acetaminophen and aspirin may cause liver damage and stomach bleeding.

Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

Do not use you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have ■ asthma ■ ulcers ■ bleeding problems ■ stomach problems that last or come back, such as heartburn, upset stomach, or pain

Ask a doctor or pharmacist before use if you are taking a prescription drug for ■ diabetes ■ gout ■ arthritis ■ anticoagulation (blood thinning)

Stop use and ask a doctor if ■ allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts for more than 10 days ■ redness or swelling is present ■ new symptoms occur ■ ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

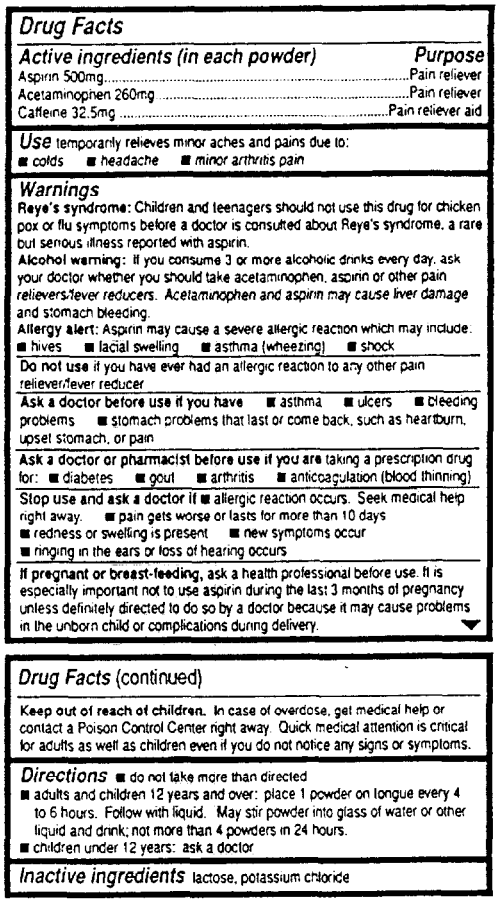
Directions ■ do not take more than directed
■ adults and children 12 years and over: place 1 powder on tongue every 4 to 6 hours. Follow with liquid. May stir powder into glass of water or other liquid and drink; not more than 4 powders in 24 hours.
■ children under 12 years: ask a doctor

Inactive ingredients lactose, potassium chloride

14 point Helvetica Regular Bold Title
6 point Helvetica Narrow Bold Headings
6 point Helvetica Narrow Subheadings
4.5 point Helvetica Narrow Text
5.5 point Leading

8 point Helvetica Narrow Bold Italic Title
7 point Helvetica Narrow Bold Italic Headings
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

Figure 2



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Drug Facts (continued)

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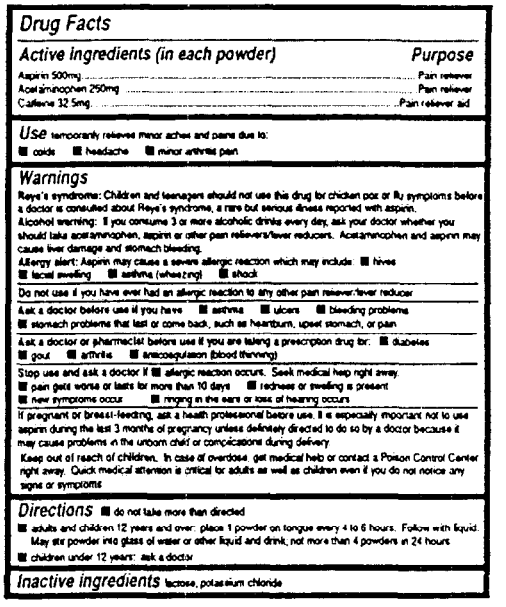
9 point Helvetica Narrow Bold Italic Title
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6.5 point Leading



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8 point Helvetica Narrow Bold Italic Title
7 point Helvetica Narrow Bold Italic Headings
4.5 point Helvetica Narrow Bold Subheadings
4.5 point Helvetica Narrow Text
5 point Leading

As the agency found in the final rule (and as illustrated here), the overall "Supplement Facts" layout, including the tabular style and the limited amount of explanatory text, allows for the use of a smaller type size in limited circumstances.

The agency also notes that in other instances it has required 6 point or larger type. For example, the agency established a 10 point minimum type size for approved patient labeling for human prescription drug and biological products (*i.e.*, "Medication Guides"). 21 CFR 208.20(a)(4); *see also* 21 CFR 610.62 (requiring the use of 12 point and 18 point type when designating antibodies in certain biologic labeling). The minimum type size for food nutritional labeling for most products is 8 point type for certain information on the label and 6 point type for all other information. Small packages (less than 12 sq. inches) may opt not to present nutritional information. *See* 21 CFR 101.9(j)(13)(i). However, small packages that present nutrition information must use a minimum of 6 point type or all upper case letters of 1/16 inches in height. 21 CFR 101.9(j)(13)(i)(B).

Finally, for various warnings and other statements required on some FDA-regulated products, a type size or letter height of 1/16th of an inch has been required. *See, e.g.*, 21 CFR 101.93(e) ("letters of a type size no smaller than one-sixteenth inch"); 310.516(c)(1) ("minimum letter size shall be one-sixteenth of an inch in height . . . letter heights pertain to the lower-case letter 'o' or its equivalent that shall meet the minimum height standard"); 701.3(b) ("letters not less than 1/16 of an inch in height"); 740.2(a) ("in no case may the letters and/or numbers be less than 1/16 inch in height.").[14]

In short, the agency considered the labeling specifications for other product categories in developing the final OTC labeling rule. The agency also considered, however, the unique demands of OTC drug labeling, along with the strong trend in the OTC drug industry toward 6 point type, and determined that a type size larger than that allowed in limited circumstances for other categories of products such as dietary supplements was justified and reasonable.

* * *

The agency has carefully reviewed the issue of type size, including the points and materials CHPA highlighted in comments to the proposed rule and in correspondence and feedback meetings over the last several months. The agency concludes that there is no need to delay implementation of the rule to continue to consider this issue.

D. Single Use Packages, Convenience Packages, and Extended Text Labeling

The petition states that additional time is needed to resolve the labeling of single use and

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[14]Applying the analysis discussed in section C.2 of this response, if the minimum letter size permitted is 1/16 of an inch, a type size as large as 8 or 9 points may be needed in some instances to ensure that the smallest letter is no smaller than 1/16 of an inch. The limited instance in which the agency has allowed 1/32 inch type (21 CFR 701.3(p)) may require about 4.5 point type.

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: AUG 28 2000

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[ ] This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment